DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 11, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 09

Lt. Col. Linda M. Adams
Commander, 28th Medical Support Squadron
Ellsworth Air Force Base
2900 Doolittle Drive
Ellsworth AFB, South Dakota 57701

Dear Colonel Adams:

We are writing to you because on September 13, 2001, your mammography facility was inspected by a representative of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 and Level 2 findings at your facility:

Level 1 Non-Compliance:

1. The system to communicate results is inadequate for Ellsworth Air Force Base because there is no system in place to provide timely medical reports for all patients.

   Based on the information provided, including peer review evaluations of your former on-site radiologist, FDA finds no evidence indicating that there has been a negative impact on the quality of mammography performed at your facility. However, due to the small number of mammography exams included in the process, your facility should consider performing another peer review, focusing on additional mammography exams.

Level 2 Non-Compliances:

2. The mammography processor equipment evaluation (by a medical physicist) for processor [redacted] Room 1K14, was not done prior to clinical use.

3. The measured fog density is equal to 0.11 for darkroom 1K13.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Sharon K. Thoma

Sharon K. Thoma
Acting Director
Minneapolis District

CAH/ccl

xc: Priscilla F. Butler
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